JC07 Rec'd PCT/PTO 3 1 DEC 2001

TRANSMITTAL LETTER	TO THE UNITED STATES	Attorney Docket No. 01234				
DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. Application No. (if known,						
CONCERNING A FILING	UNDER 35 U.S.C. 371	see 3100/019446				
INTERNATIONAL APPLICATION NO. PCT/EP00/06060	INTERNATIONAL FILING DATE June 29, 2000	PRIORITY DATE CLAIMED June 29, 1999				
TITLE OF INVENTION						
METHOD FOR ADJUSTING OR CONTRO APPLICANT(S) FOR DO/EO/US	OLLING THE DIET AND/OR A PERSON'S CON	SUMPTION				
Heiner Stegmann						
Applicant herewith submits to the United Sta	ates Designated Office (DO/EO/US) the following	items and other information:				
 This is a SECOND or SUBSEQUE This is an express request to begin examination until the expiration of 	ns concerning a filing under 35 U.S.C. 371. ENT submission of items concerning a filing under national examination procedures (35 U.S.C. 371(f)) the applicable time limit set in 35 U.S.C. 371(b) at Preliminary Examination was made by the 19 th mo	at any time rather than delay and PCT Articles 22 and 39(1).				
5. A copy of the International Applica a. \(\subseteq \) is transmitted herewith (required) b. \(\subseteq \) has been transmitted by the c. \(\subseteq \) is not required, as the application of the International A Amendments to the claims of the International A a. \(\subseteq \) are transmitted herewith (continuous)	nired only if not transmitted by the International Bu International Bureau. ation was filed in the United States Receiving Office pplication into English (35 U.S.C. 371(c)(2)). International Application under PCT Article 19 (35 Uniternational Bureau).	ce (RO/US).				
b. have been transmitted by the International Bureau. c. have not been made; however, the time limit for making such amendments has NOT expired. d. have not been made and will not be made. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4). A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5).						
Items 11 to 16 below concern document(s)	or information included:					
An Information Disclosure Statemed 2. As assignment document for record 43. A FIRST preliminary amendment. A SECOND or SUBSEQUENT present 4. A substitute specification. 15. A change of power of attorney and Other items or information: German text to which declaration is	ling. A separate cover sheet in compliance with 37 eliminary amendment.	CFR 3.28 and 3.31 is included.				



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Dkt. 01234

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Group Art Unit:

HEINER STEGMANN

Examiner:

Serial No.: US National Phase of

PCT/EP00/06060

Filed: concurrently herewith

For: METHOD FOR ADJUSTING OR CONTROLLING THE DIET

AND/OR A PERSON'S CONSUMPTION

PRELIMINARY AMENDMENT

Honorable Assistant Commissioner for Patents Washington, DC 20231

Sir:

Before calculation of the filing fee, please amend the above-identified application as follows:

IN THE CLAIMS:

Please amend the claims as set forth hereinbelow and in the attached appendix:

Page 9, lines 1-3: WHAT IS CLAIMED IS:

- 3. (Amended) Method according to claim 1, characterized by the fact that for determining the performance capacity the individual anaerobic threshold of the person is measured or determined.
 - 4. (Amended) Method according to claim 1, characterized

by the fact that for determining the performance capacity a scaling of the performance measured above the individual anaerobic threshold occurs according to the lactate accumulation rate ΔA .

- 5. (Amended) Method according to claim 1, characterized by the fact that the stress is used as a basis for the IAT and the lactate accumulation rate ΔA in determining the nutrition and/or the consumption of a person with regard to his/her carbohydrate and/or fat and/or protein percentages.
- 6. Method according to claim 1, characterized by the fact that the individual anaerobic threshold according to Stegmann is used a basis for determining the nutrition and/or consumption of the person with regard to his/her carbohydrate and/or fat and/or protein percentages.
- 7. (Amended) Method according to claim 1, characterized by the fact that when stress occurs in a person over an extended period of time below his/her individual anaerobic threshold, the fat percentage of the nutrition is adjusted comparatively higher than the carbohydrate and the protein percentages.
- 8. (Amended) Method according to claim 1, characterized by the fact that with a lactate accumulation rate ΔA against ΔA_{max} the protein percentage of the nutrition is adjusted up to several times as high as with $\Delta A = 0$.

9. (Amended) Method according to claim 1 for determining the lactate accumulation rate ΔA , comprising the steps of:

measuring the time-dependent lactate concentration change beyond the individual anaerobic threshold,

adjusting a measurement curve to measurement values gained this way, in which the lactate concentration in relation to time is plotted,

determining a first gradient in the measurement curve at a time $t_{\text{\tiny IAT}}$ that corresponds to the individual anaerobic threshold,

determining at least one additional gradient in the measurement curve at a time $t_{\rm x}$ with $t_{\rm x}$ > $t_{\rm IAT}$

subtracting the second gradient from the first gradient to determine a difference, which represents the lactate accumulation rate ΔA .

10. (Amended) Method according to claim 1, characterized by the fact that for determining the performance capacity, different types of stress such as running tests, swimming tests, stepping tests, ergometry methods with graduated or continuous stress increase with and without breaks are used.

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REMARKS

The claims have been amended to delete all multiple dependencies, and to generally place the claims in better form for US practice.

Respectfully submitted,

Ira J. Schultz

Registration No. 28666

APPENDIX

IN THE CLAIMS:

Page 9, lines 1-3: [Patent Claims

Method for Adjusting or Controlling a Person's Nutrition

and/or Consumption] WHAT IS CLAIMED IS:

- 3. (Amended) Method according to claim 1 [or 2], characterized by the fact that for determining the performance capacity the individual anaerobic threshold of the person is measured or determined.
- 4. (Amended) Method according to [at least one of the previous claims] claim 1, characterized by the fact that for determining the performance capacity a scaling of the performance measured above the individual anaerobic threshold occurs according to the lactate accumulation rate ΔA .
- 5. (Amended) Method according to [at least one of the previous claims] claim 1, characterized by the fact that the stress is used as a basis for the IAT and the lactate accumulation rate ΔA in determining the nutrition and/or the consumption of a person with regard to his/her carbohydrate and/or fat and/or protein percentages.
- 6. Method according to [at least one of the previous claims] claim 1, characterized by the fact that the individual anaerobic threshold according to Stegmann is used a basis for determining the nutrition and/or consumption of the person

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with regard to his/her carbohydrate and/or fat and/or protein percentages.

- 7. (Amended) Method according to [at least one of the previous claims] claim 1, characterized by the fact that when stress occurs in a person over an extended period of time below his/her individual anaerobic threshold, the fat percentage of the nutrition is adjusted comparatively higher than the carbohydrate and the protein percentages.
- 8. (Amended) Method according to [at least one of the previous claims] claim 1, characterized by the fact that with a lactate accumulation rate ΔA against ΔA_{max} the protein percentage of the nutrition is adjusted up to several times as high as with $\Delta A = 0$.
- 9. (Amended) Method according to [at least one of the previous claims] claim 1 for determining the lactate accumulation rate ΔA , [characterized by the following procedural steps] comprising the steps of:

measuring the time-dependent lactate concentration change beyond the individual anaerobic threshold,

adjusting a measurement curve to measurement values gained this way, in which the lactate concentration in relation to time is plotted,

determining a first gradient in the measurement curve at a time t_{IAT} that corresponds to the individual anaerobic

threshold,

determining at least one additional gradient in the 'measurement curve at a time t_x with $t_x \,>\, t_{\text{IAT}}$

subtracting the second gradient from the first gradient to determine a difference, which represents the lactate accumulation rate ΔA .

10. (Amended) Method according to [at least one of the previous claims] claim 1, characterized by the fact that for determining the performance capacity, different types of stress such as running tests, swimming tests, stepping tests, ergometry methods with graduated or continuous stress increase with and without breaks are used.

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Description

Method for Adjusting or Controlling a Person's Nutrition and/or Consumption

The invention relates to a method for adjusting or controlling the nutrition and/or consumption of carbohydrates and/or fats and/or proteins of a person who is subjected to a certain physical stress.

The invention relates in particular to a method for determining necessary nutrition and/or nutritional therapeutic substances for controlling a person's nutrition by indirectly determining his/her individual carbohydrate, fat and protein shares in the provision of his/her energy level standardized stress tests and the controlled consumption of such shares while taking the results that were determined in the standardized stress tests into consideration.

Carbohydrates, fats and proteins are substrates, which are metabolized in the muscles for energy production, e.g. ATP production. During the transition from a resting position to a state of strong stress, great changes occur in the muscle's metabolism. Due to the increased need for energy, especially the rate of substrate conversion increases drastically.

In this context it is of great importance that in the muscle under stress also the conversion rate ratios of the individual

substrates to each other change tremendously, i.e. the percentage of carbohydrate, fat and protein conversion in the overall substrate conversion process is regulated in the muscle as a function upon stress.

The invention is based on the problem of developing a method of the above-described kind in such a way that with simple measures a reliable adjustment or control of a person's nutrition and/or consumption as a function upon the relevant stress in relation to the carbohydrate and/or fat and/or percentages occurs, wherein especially among people who are exposed to great stress such as athletes or sick or elderly people a controlled adjustment of the supplied carbohydrates and/or fats and/or proteins or the consumption occurs. According to the invention, the problem is largely resolved by the fact that for the control and/or adjustment of the person's nutrition and/or consumption his/her performance capacity is determined by determining characteristic performance capacity parameters and that as a function upon the determined performance capacity the carbohydrate and/or fat and/or protein percentage requirements and/or consumption by the person is determined, by basing the calculation on the stress that is decisive for nutrition and/or consumption.

According to the invention it is suggested that, for

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controlling and/or adjusting the nutrition and/or consumption of nutrients in a person, his/her performance capacity is determined by determining characteristic performance capacity parameters and that his/her need for and/or consumption of carbohydrates and/or fats and/or proteins in his/her food is determined as a function upon the determined performance capacity of the person, basing the calculation on stress-specific substrate mixture ratios that are decisive for nutrition and/or consumption. Substrate mixture ratios should be interpreted as the carbohydrate and/or fat and/or protein percentages.

In particular the invention provides for the fact that for the purpose of determining the performance capacity of the person the heart rate and/or blood pressure and/or ergospirometric parameters and/or lactate concentration in the blood is measured or determined as a function upon the stress.

In a preferred embodiment of the invention, a scaling to a lactate accumulation rate ΔA for occurs the purpose determining the performance capacity above the individual threshold, wherein in particular accumulation rate ΔA is used as a basis for determining the nutrition and/or consumption of the person in relation to his/her protein percentage from glucogenic amino acids.

A method for determining the lactate accumulation rate ΔA

is characterized by the following procedural steps:

measuring the time-dependent lactate concentrate change beyond the individual anaerobic threshold,

adjusting a measurement curve to measurement values gained this way, in which the lactate concentrate in relation to time is entered,

determining a first gradient in the measurement curve at a time $t_{\text{\tiny IAT}}$ that corresponds to the individual anaerobic threshold,

determining at least one additional gradient in the measurement curve at a time t_x with $t_x \, > \, t_{\text{\tiny IAT}}$

subtracting the second gradient from the first gradient to determine a difference, which represents the lactate accumulation rate ΔA .

In order to be able to provide information about the stress-specific regulation of the substrate metabolism of test subjects, initially the performance capacity stress ability of these test subjects must be determined with a standardized test, which allows the possibility of estimating the aerobic/anaerobic transition. Such tests can be conducted with various methods.

For the determination of the performance capacity, different stress types can be applied such as running tests, swimming tests, stepping tests, ergometry methods, e.g. bicycle, treadmill, rowing ergometry with gradual and/or continuous stress

increase, performed with or without breaks.

Alternatively, the following parameters, which can be measured or deduced from the measurement parameters, can be used to determine the performance capacity:

heart rate (HF) under stress

HF max (with stress)

HF submax (anaerobic-aerobic transition: Conconi test)

HF related performance (physical working capacity)

HF related oxygen intake

blood pressure (RR)

stress blood pressure (systolic)

blood pressure amplitude

ergospirometric parameters

minute volume (AMV)

oxygen intake (VO₂)

 $maximum VO_2 (VO_2 max)$

respiration rate (AF)

carbon dioxide emission (VCO₂)

respiratory equivalent $(A\ddot{A} = AMV / VO_2)$

oxygen pulse (VO₂ / HF)

acid/base status, pH value

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respiratory quotient (RQ) ventilatory equivalent for CO_2 and O_2 anaerobic threshold (according to Wasserman) individual anaerobic threshold (according to Stegmann)

lactate concentration in blood

IATs according to Stegmann

ΔA according to Stegmann

Lactate threshold concepts with fixed lactate concentration and $\ensuremath{\mathsf{gradients}}$

model-related parameters deduced from the lactate curve parameters deduced from lactate curve and ergospirometric data.

The most exact method however is the determination of the lactate performance curve in the graduated test with determination of the individual anaerobic threshold according to Stegmann (IATs) as well as the IATs-adjusted lactate accumulation rate ΔA .

The lactate performance curve of a human being can be changed only very slowly through training and/or lifestyle. From its course, information can therefore be deduced about the performance and training behavior of a human being over an extended period of time, i.e. the lactate performance curve of a person can be interpreted as "medium-term memory" of his/her

lifestyle.

In relation to the IATs and the ΔA value of a test subject and with consideration of the above-described explanations, the following general statements with regard to the carbohydrate, fat and protein consumption of a test subject under stress can be made (ΔA_{max} = largest determinable ΔA value in a test subject)

Stress Intensity	Duration	СН	Fat	Protein
Start and graduated start	very short[s]	+	++	+++
$>$ IATs, $\triangle A$ -> $\triangle A_{max}$	short[≤ min]	+	++	+++
$>$ IATs, $\triangle A << \triangle A_{max}$	short[6-10 min]	++	++	++
≤IATs	short[> 2 min] -	++	++	+
≤ IATs	medium[< 60 min]]++	++	+
≤ IATs	long[>60 min] +	++	+++	++

The relative stress intensities and stress duration periods, to which a person is exposed e.g. in his/her daily life or during sports activities, therefore regulate the ratios of carbohydrate, fat and protein percentages in his/her nutrient consumption. These ratios are shown as a rough outline in the above table. These results can be applied directly for the development of required formula nutrition or nutritional therapeutics that have been adjusted to the

individual performance capacity so as to avoid nutritional deficiencies.

When adjusted to the individual anaerobic threshold and/or the adjusted lactate accumulation rate ΔA , the need for carbohydrate, fat and protein percentages as a function upon stress intensity and stress duration – in accordance with the table – offers the possibility to expose a test subject to stress in such a controlled manner that carbohydrates and/or fat percentages are used in the desired scope.

The method according to the invention thus represents a connection between knowledge about stress-specific substrate consumption, i.e. carbohydrate, fat and protein consumption of a person, and the possibility to evaluate this specificity based on performance tests and to deduce individual nutritional recommendations or control the substrate consumption through appropriate selection of training modes.

Patent Claims

Method for Adjusting or Controlling a Person's Nutrition and/or Consumption

1. Method for adjusting or controlling the nutrition and/or consumption of carbohydrates and/or fats and/or proteins in a person subjected to stress, characterized by the fact that for the control and/or adjustment of the nutrition and/or consumption of nutrients in a human being his/her performance capacity is determined by determining characteristic performance capacity parameters and that as a function upon the determined performance capacity the carbohydrate and/or fat and/or protein percentage requirements are determined and/or their consumption by a person, while basing the calculation on the stress, which is decisive for the nutrition and/or consumption.

2. Method according to claim 1, characterized by the fact that, for determining the performance capacity, the heart rate and/or blood pressure and/or ergospirometric parameters and/or lactate concentration in the blood are measured or determined as a function upon the stress.

- 3. Method according to claim 1 or 2, characterized by the fact that for determining the performance capacity the individual anaerobic threshold of the person is measured or determined.
- 4. Method according to at least one of the previous claims, characterized by the fact that for determining the performance capacity a scaling of the performance measured above the individual anaerobic threshold occurs according to the lactate accumulation rate ΔA .
- 5. Method according to at least one of the previous claims, characterized by the fact that the stress is used as a basis for the IAT and the lactate accumulation rate ΔA in determining the nutrition and/or the consumption of a person with regard to his/her carbohydrate and/or fat and/or protein percentages.

Method according to at least one of the previous

characterized by the fact
that the individual anaerobic threshold according to Stegmann
is used a basis for determining the nutrition and/or
consumption of the person with regard to his/her carbohydrate

and/or fat and/or protein percentages.

- 7. Method according to at least one of the previous claims, characterized by the fact that when stress occurs in a person over an extended period of time below his/her individual anaerobic threshold, the fat percentage of the nutrition is adjusted comparatively higher than the carbohydrate and the protein percentages.
- 8. Method according to at least one of the previous claims, characterized by the fact that with a lactate accumulation rate ΔA against ΔA_{max} the protein percentage of the nutrition is adjusted up to several times as high as with $\Delta A = 0$.
- 9. Method according to at least one of the previous claims for determining the lactate accumulation rate ΔA , characterized by the following procedural steps

measuring the time-dependent lactate concentration change beyond the individual anaerobic threshold,

adjusting a measurement curve to measurement values gained this way, in which the lactate concentration in relation to time is plotted,

determining a first gradient in the measurement curve at a

time $t_{\mbox{\scriptsize IAT}}$ that corresponds to the individual anaerobic threshold,

determining at least one additional gradient in the measurement curve at a time t_x with $t_x \,>\, t_{\text{TAT}}$

subtracting the second gradient from the first gradient to determine a difference, which represents the lactate accumulation rate ΔA .

10. Method according to at least one of the previous claims,

characterized by the fact

that for determining the performance capacity, different types of stress such as running tests, swimming tests, stepping tests, ergometry methods with graduated or continuous stress increase with and without breaks are used.

11. Method for adjusting and/or controlling the nutrition and/or consumption of carbohydrates and/or fats and/or proteins of a person who is subjected to stress characterized by the fact that for the control and/or adjustment of the nutrition and/or consumption of nutrients in a human being his/her performance capacity is determined by determining characteristic performance capacity parameters and that the need for and/or consumption of carbohydrates and/or fats and/or proteins in the

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food is determined as a function upon the determined performance capacity of the person, while basing the calculation on the stress-specific substrate mixture ratios that are decisive for the nutrition and/or consumption.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

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